CUSTOMER: _____
REFERENCE: _____

833HC-E SERIES VACUUM/GRAVITY STEAM STERILIZERS FOR HEALTHCARE APPLICATIONS

PRODUCT SPECIFICATION

PRODUCT

The Model 833HC-E Vacuum/Gravity Steam Sterilizer employs both gravity/downward displacement with positive pulse conditioning and pressure/vacuum pulsing for dynamic air removal. Up to 17 cycles can be easily accessed in two easy steps. Custom cycle names can be designated for each cycle and each cycle can be reconfigured for easy access. All cycle phases are sequenced and monitored by the control system, providing both audible and visual notification of deviation from certain operating parameters.

APPLICATION

For general-purpose gravity or vacuum steam sterilization of hospital instruments and supplies. The selectable temperature range is from 230°F to 275°F (110°C to 135°C) and from 219°F to 275°F (104°C to 135°C) for liquid cycles. Typical applications include wrapped and unwrapped porous and non-porous hard goods, gowns or towel packs and liquids in self-venting or unsealed containers. The liquid exhaust is microcomputer controlled for linear and consistent liquid cool down, programmable within a specified range.

MODEL SELECTION

☐ = Standard O = Optional

CHAMBER DIMENSIONS

26.5" (672mm) wide x 62" (1575mm) high

☐ 42" long (1067mm) 39.6 Cu Ft (1120L)
☐ 76" long (1930mm) 72.0 Cu Ft (2040L)

SINGLE DOOR UNIT

☐ Recessed Only

SINGLE DOOR DESIGNATIONS

☐ Right Hand Hinged, Left Hand Control Column
☐ Left Hand Hinged, Right Hand Control Column (shown)

DOUBLE DOOR UNIT

☐ Recessed both ends

DOUBLE DOOR DESIGNATIONS

☐ Control End (CE) Door—Right Hand Swing, Left Hand Control Column, Remote End (RE) Door Swing and Column opposite.

☐ Control End (CE) Door—Left Hand Swing, Right Hand Control Column, Remote End (RE) Door Swing and Column opposite.

CONTROL PANEL LOCATION

☐ On Unit
O Wall Mounted

Floor Mounting

☐ Depressed Pit Mounted for level-loading
O Floor Mounted with Scissor Lift
O Floor Mounted for use with Transfer Carriage

ELECTRICAL SUPPLY - Sterilizer

☐ 115V, 1Ph 50/60 Hz
O 230V, 1Ph 50/60 Hz

STEAM SOURCE

☐ House steam

LANGUAGE (SELECT ONE)

☐ English
O French
O Spanish

LOADING EQUIPMENT

☐ 4003 Floor Loading Cart with 3 Shelves, Qty. _____
☐ 4004 Transfer Carriage, Qty. _____
☐ 4003RC Floor Loading Cart for Transfer, Qty. _____

OTHER STERILIZER ACCESSORIES & OPTIONS

O Air Compressor
O Auto Blowdown Control for stand-alone electric boiler
O Steam Separator Tank for Auto Blowdown

- O Water Saver Package for Vacuum Ejector Models only
  - O 115V
  - O 230V
- O 115V Water Chiller Unit for Water Saver
- O House chilled water COIL in lieu of electric Water Chiller
- O Limited Access Kit (Hinged control tower)
- O Uninterrupted Power Supply (UPS). Provides control power for up to 30 minutes to complete a cycle in process. (Vacuum ejector models only)
- O T-DOC Package for Instrument Traceability & Asset Management (including T-DOC Cycle) *
- O Getinge Online for remote connectivity to view real-time sterilizer process data *

  * Requires CAT-5 type Ethernet cable to connect hospital's network or existing internet connection to the machine's NetCOM card. (Cabling is client's responsibility – SEE ARRANGEMENT DRAWING)

QUALITY STATEMENT

Confidence in the Getinge Group is the most important quality criterion. This must be the hallmark of all our external and internal commitments, activities and products. Products and services supplied by Getinge must conform to the agreed terms and expectations to ensure recommendations for further business. The achievement of these quality goals is the basis for a continued competitive and successful enterprise.

STANDARDS AND CODES

The sterilizer shall comply with or meet the requirements of:

- ASME (Section VIII, Division 1) Code for Pressure Vessels
- Canadian Registration Number (CRN) Pressure Vessel Design
- Uniform Plumbing Code
- ETL Listed to UL 61010A-1 and UL61010A-2-041
- ETL Listed to IEC 61010-1 and IEC 61010-2-040
- cETL Listed to CSA C22.2 Nos. 1010.1 and 1010.2.041
- Seismic Anchoring Requirements per CBC
- Cycle Performance Validated to ANSI/AAMI ST8:2008

STANDARD SAFETY FEATURES

Steam interlock door switch – Prevents steam from entering the chamber when the door is not sealed.

Steam safety valves – Ensure that the pressure in the chamber and/or jacket do not over-pressurize.

Door obstruction shut-off – Safety clutch stops the door movement if an obstacle is encountered. After a short time-out the motor will be shut down.

Analog chamber gauges – Needle-style gauges provide real-time pressure readings in the jacket and chamber even in the event of a micro-computer control system outage.

Program check – The control system validates all user-programmed / adjusted cycle parameters against sterility assurance levels for safe, effective cycle recommendations. A warning appears if user's parameters do not satisfy the program's SAL calculation.

Password protected menu tree – All levels of cycle changes and parameter adjustments require supervisor password or service password.

Abort alert – Aborted cycles result in a warning message that requires user intervention before the chamber can be re-opened.

Gasket retract valve – Allows door gasket to be manually retracted in the event emergency access to the chamber becomes necessary.

Door safety baffle – In the unlikely event of a catastrophic door failure, the gasket will blow out and a baffle at the chamber mouth directs steam away from areas where users might be working.

W**ater alarm** – High water levels in the drain that cannot be corrected automatically will result in an audible alert.

Door motion alarm – An audible alarm chirps throughout the opening and closing motion of the power automatic door.

Power door guards – Panels cover moving parts of the door as it slides into locked position.

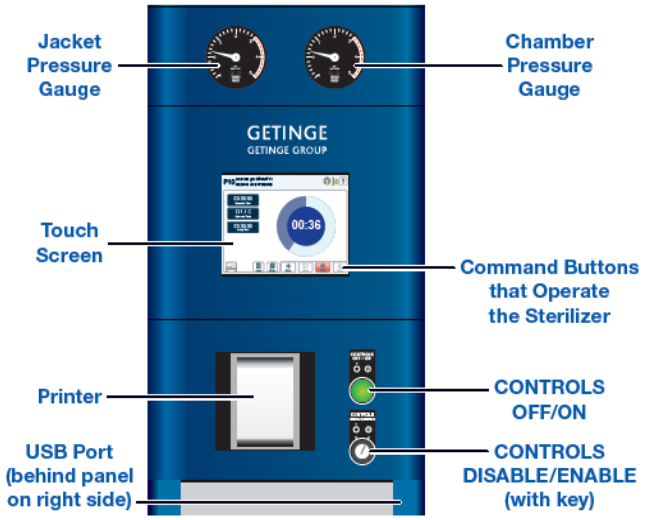
Heat guards and insulation – Heat guards and insulation are standard on surfaces where operators routinely come into contact with the door or chamber opening during loading and unloading operations.

CONTROL SYSTEM

Getinge Sterilizers employ the PACS 3500 modular PLC control system to monitor and control all sterilizer operations and functions. The control system is factory programmed with standard sterilizing cycles. Each cycle is adjustable to meet specific reprocessing requirements. All user accessible control functions can be changed with appropriate password using the touch screen interface panel.

The E-Series control system consists of a user interface panel (called AVANTI), the CPU controller, a NetCOM communications card, a thermal printer, mechanical chamber and jacket pressure gauges, status indicators, and controls On/Off switch. A key lock is provided to insure all door power is disconnected when working in the chamber.

Controls are located next to the door in a vertical column for convenience. If specified, the control column can be located remotely from the sterilizer with up to 32.8 feet (10 m) of cable. An RS 232 port is provided for serial communications for central data collection or remote service analysis and is ready for T-DOC connection. **The AVANTI user interface panel is a durable 8.4 inch diagonal SVGA color touch screen display.**



Audible and visual feedback is provided to users when a selection is made or a fault message is displayed. Temperature can be set, controlled and displayed in degrees Celsius or Fahrenheit. Pressure is preset to be controlled and displayed in PSI. AVANTI user interface display is mounted at both ends of the pass-thru sterilizer for full control capabilities at either door.

Cycle Performance Documentation

The Getinge 833 E-Series sterilizer provides three standard means for cycle documentation:

- Paper printer
- USB flash memory drive
- NetCOM Ethernet connection

The **paper printer** documents cycle performance using special thermal paper for a permanent record. Thermal printing allows for quiet operation. The printer is located on the control panel below the touch screen and documents the following on a 200-dpi dot matrix printer with 1.88" (47.6mm) wide paper:

- Process start time and date, sterilizer name and number, daily cycle number and total cycle count
- Cycle selected with time and temperature, with other adjustable parameters identified
- Cycle phase transition points, temperature, pressure and total cycle time
- Process fault information messages with time of occurrence
- Parameter Check provided a calculated, numeric process lethality
- Summary verification of time at selected temperature (min/max exposure values)
- Cycle verification signature line

Paper roll is replaced by a “drop in and quick feed” method and the printed strips can be either accumulated on an automatic take-up reel, or torn off for individual cycle storage. A paper feed switch is provided, along with a switch for printing a duplicate of the “last cycle”.

For backup / informational purposes, the same **cycle performance data is also automatically sent to a USB flash drive port** in the control tower. A USB memory module is supplied with each unit and will hold approximately 10,000 cycles. **This backup cycle data can be sent directly to a USB printer in lieu of the USB flash drive.**

A NetCOM communications card is provided standard as part of the control system of each unit. The NetCOM is providing all of the cycle performance data to the USB port device. NetCOM also **supports a separate Ethernet connection** between the sterilizer and the following external data management systems (See Note):

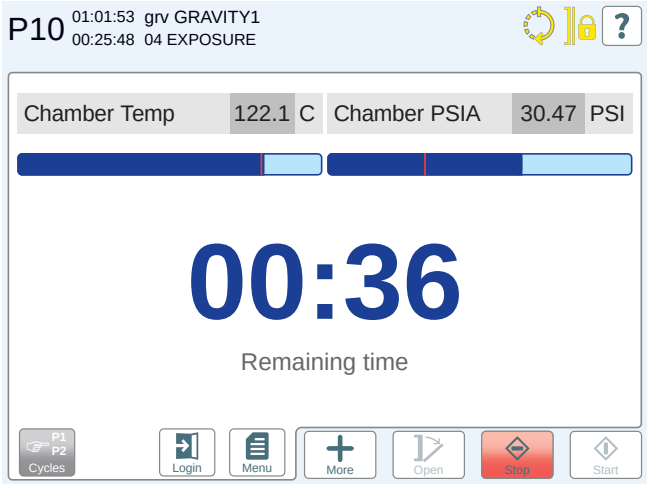
- T-DOC Instrument Tracking and Asset Management
- T-DOC Data Logging storage and printing
- Getinge Online web based remote monitoring

Note: *Separate equipment and setup required, including network Ethernet cable drop by customer for each sterilizer. Internet accessibility may be required. Refer to arrangement drawing and contact your Getinge representative for details.*

AVANTI User Interface Features

The AVANTI touch screen serves as the user’s command and control center. The screen is divided into specific sections to display cycle selection, operation and process performance information in a consistent manner.

Bar Graph – Displays temperature and pressure in a bar graph with a large, easy to read digital time remaining display in the center. Cycle time is the average of the last three cycles of each cycle type.



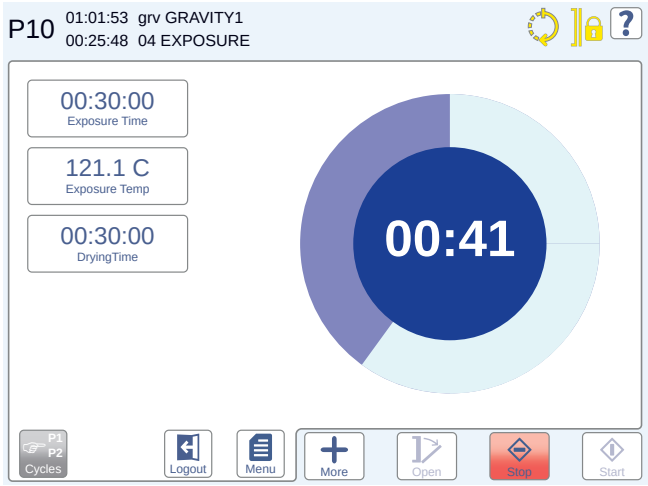
The **Button Field** across the bottom displays the application buttons that are used to give commands –

- **Cycle Select:** Tap to access and select from 23 recommended factory cycles
- **Login:** Tap to access password protected features
- **Menu:** Tap to select operating screen displays
- **Door controls:** Use to open, close and seal doors
- **Cycle Start:** Turns green when conditions are OK to start a cycle. Tap to start cycle.

Four process display screens are available to show important cycle information in different formats for ease of recognition.
The optional screens are:

- Bar Graph
- Circle Graph
- Details Display
- Plot Graph

Circle Graph: Displays remaining time as a large easy to read graph that fills the circle as time elapses. Cycle time is the average of the last three cycles for each cycle type.



The **Status Field** across the top of the touch screen identifies the selected cycle number, cycle name and current cycle phase on the left side. Cycle status and door status are displayed on the right side. Text alarm messages and non-critical system messages are displayed in the central area.

The **Middle Field** of the display screen shows actual, real time cycle information in the optional format selected. Cycle parameters such as exposure time, exposure temperature, or drying time can be changed with the proper password clearance. Simply "tap" the value on the screen and input the new parameter value. Changes must be acknowledged and saved by the user.

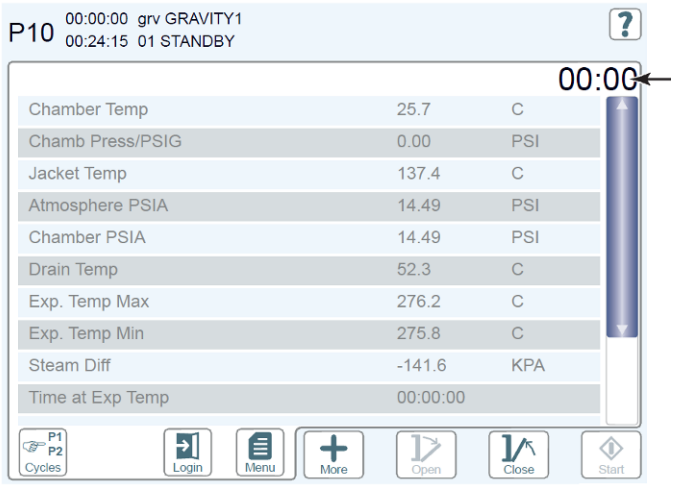
Note: *Adjustment of time and temperature parameters requires user validation of the cycle efficacy. Factory recommended cycles are validated to ANSI/AAMI ST8.*

User Access: The PACS control system is operated via an easy to use "menu system". By default the user has access to the cycle selection, door control and cycle start. Users can run only validated cycles. Access to other areas such as running test cycles, re-setting parameters, calibration, service and maintenance is controlled by pre-defined password access. Refer to the MENU tree in the User Manual.

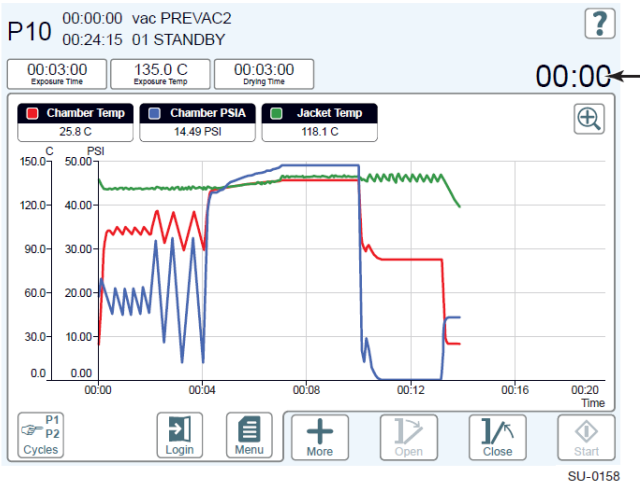
Tap the MENU button to see the following sub-menus:

- System Menu
- Process Screen
- Documentation – Password Required
- Alarm History

Details Display: When the Details Screen is selected, the center area of the screen displays real time process data in text form. The remaining cycle time is displayed to the right of the text field.



Plot Graph. The start screen displays a plot graph of various process parameters. Each process parameter is displayed in contrasting colors. Additional process parameters are displayed in the status field. The remaining time is displayed to the right of the status field.



Supervisor Access: A start-up password is provided with the sterilizer for establishing first time password access for defined users / supervisors. Use the special "supervisor password' to access and setup the following: (Refer to the MENU tree in Appendix C of the User Manual)

- Access the system "About" section to identify the model and software version number
- Add new users with passwords
- Adjust system menu for setting the calendar
- Select language, date format, and temperature and pressure measurement
- Re-order and/or re-name cycles
- Edit cycle parameters
- Activate utilities control feature to shut-off water and steam to the sterilizer to conserve energy
- Print the last cycle

FACTORY DEFAULT CYCLES

MODEL 833HC-E (17 Cycles total)

- **275°F (135°C) Prevacuum Cycle (6 total)** – For sterilizing double wrapped instrument trays up to 25 Lb. (11.3 kg) per tray – or fabric packs.
  > 275°F (135°C) sterilize temperature
  > 3 minutes exposure
  > 16 minutes dry time

- **270°F (132°C) Prevacuum Cycle (1 total)** – For sterilizing double wrapped instrument trays up to 25 Lb. (11.3 kg) per tray – or fabric packs.
  > 270°F (132°C) sterilize temperature
  > 4 minutes exposure
  > 16 minutes dry time

- **250°F (121°C) Gravity Cycle (3 total)** – For sterilizing double wrapped instrument trays up to 25 Lb. (11.3 kg) per tray – or fabric packs.
  > 250°F (121°C) sterilize temperature
  > 30 minutes exposure
  > 30 minutes dry time

- **275°F (135°C) Gravity Cycle (3 total)** – For sterilizing double wrapped instrument trays up to 25 Lb. (11.3 kg) per tray – or fabric packs.
  > 275°F (135°C) sterilize temperature
  > 10 minutes exposure
  > 30 minutes dry time

- **270°F (132°C) Gravity Cycle (1 total)** – For sterilizing double wrapped instrument trays up to 25 Lb. (11.3 kg) per tray – or fabric packs.
  > 270°F (132°C) sterilize temperature
  > 15 minutes exposure
  > 30 minutes dry time

- **273°F (134°C) Vac Bowie & Dick Test Cycle (1 total)** – For conducting B-D tests of prevacuum sterilizer using a validated test pack.
  > 273°F (134°C) sterilize temperature
  > 3-1/2 minutes exposure
  > zero minutes dry time

- **268°F (131°C) Vacuum Leak Test (1 total)** – For testing the vacuum integrity of the sterilizer's piping. Note: Vacuum leak test parameters are not adjustable.
  > 268°F (131°C) sterilize temperature
  > 3 minutes exposure
  > 15 min dry time; 5 min equalize; 15 min test

- **250°F (121°C) Liquid Cycle (1 total):** For sterilizing liquids in vented or open 1000 mL (34 fluid oz.) or smaller containers. **Important:** Liquid cycles are not intended for sterilization of liquids used in direct contact with patients.
  > 250°F (121°C) sterilize temperature
  > 45 minutes exposure
  > Dry time: Not applicable

Note: *Selection of time and temperatures other than factory recommendations require operator verification of the cycle efficacy. Factory default cycles were validated to ANSI/AAMI ST8.*

CYCLE PROGRESSION

- **Gravity/Wrapped Goods**
  (Pressure pulse conditioning)
  a. **Conditioning**—steam flows into the chamber for a timed period, followed by a series of positive pressure pulses to remove chamber air.
  b. **Heat-Up**—to selected temperature.
  c. **Exposure**—selected chamber temperature is attained and timed.
  d. **Exhaust**—chamber vented to atmospheric pressure.
  e. **Dry**—filtered air is drawn through chamber for the duration of time selected. (Either Gravity or Vacuum Dry is selectable; Vacuum Dry is recommended)
  f. **Cycle Complete**—signaled by a tone, light and display message on the Avanti touch screen.

- **Prevacuum/Wrapped Goods**
  (Vacuum/pressure pulsing conditioning)
  a. **Conditioning**—steam flows into the chamber for a timed period, followed by a series of pressure/vacuum pulses to remove chamber air.
  b. **Heat-Up**—to selected temperature.
  c. **Exposure**—selected chamber temperature is attained and timed.
  d. **Exhaust**—chamber vented to below atmospheric pressure.
  e. **Dry**—a vacuum is created for the duration of the time selected. Filtered air is admitted at the end of the drying time, chamber to atmospheric pressure.
  f. **Cycle Complete**—signaled by a tone, light and display message on the Avanti touch screen.

- **Liquids**
  a. **Conditioning**—steam flows into chamber for a timed period to remove air.
  b. **Heat-Up**—to selected temperature.
  c. **Exposure**—selected chamber temperature is attained and timed.
  d. **Exhaust**—an adjustable linear exhaust.
  e. **Cycle Complete**—signaled by tone, light and display message on the Avanti touch screen.

PERFORMANCE

When installed and connected to specified utility services, the system provides accurate and repeatable performance. During the timed exposure phase, the temperature will be controlled by the chamber sensor at 1.1°F (0.6°C) above the set point (± 0.1°C). Temperature selectivity is in 0.1°F (0.1°C) increments.

Timing functions are selectable in one-second increments, and accuracy is within 0.04%. Temperature is controlled by a time proportioning continuous algorithm, called Proportional Integral (PI). A battery with a 10 year life holds

programmed cycle values in memory. In the event of a power interruption, current cycle status is stored for up to 1 minute.

DESIGN CONSTRUCTION

The chamber is constructed of an inner shell reinforced by a series of “U” channels that form the outer jacket of the chamber. The gasket ring and backhead (on single door models) are formed and welded to the chamber body. Chamber and door material is 6 mm (0.236”) thick stainless steel Type SA240, 316Ti. The jacket material is also 316Ti stainless steel. **The interior chamber finish is polished to a high luster finish**. All pressure vessel construction meets ASME code requirements for working pressures up to 45 psig (310 kPa). The gasket ring holds a continuous, one-piece silicone gasket, 0.787" (20 mm) in diameter. The body assembly is thermally insulated with 1.5" fiberglass insulation and is double thick between the jacket “U” channels.

A steam baffle is provided to prevent condensation from wetting the load. An extra threaded opening permits passage of thermocouple leads to monitor interior and load temperatures. Steam connection to the chamber and jacket is 316L stainless steel material. A manual gasket retract valve is provided for emergency chamber access.

Door Operation

The door operation is powered by an electric motor and is actuated by a switch. The open motion is in two steps. First, a slide to clear the door locking pins, then it swings open. The door will stop automatically if an obstruction is encountered. In an emergency, the power door can be opened manually by a qualified technician. At the beginning of the cycle, steam pressure behind the gasket automatically seals the door and retracts automatically at the end of the cycle. Sealing is positive and consistent. The gasket is recessed for added protection and long life. Once the cycle begins and the chamber is pressurized, the door cannot be opened. A safety switch prevents steam from entering the chamber when the door is not in the closed and sealed position. The door is insulated with fiberglass insulation and covered with a stainless steel panel.

Paneling

The control panel and paneling is constructed of nominal 0.050’’ (1.27 mm) No. 3 brushed finish stainless steel and is hinged for easy access to electronic components. The trim panels are built-in to fit within a recessed wall.

CONSERVATION FEATURES

The 800 Series is provided standard with a vacuum water ejector for dynamic removal of air from the chamber. Specify the Water-Saver or **Water-Saver with Water-Chiller** option to reduce water consumption by as much as 80% or greater depending on load and cycle conditions**. Building chilled-water** loop can be used to cool down the recirculating vacuum ejector water in lieu of the electric water chiller.

Validated tray loads increased from 16 pounds (7.3 Kg) to 25 pounds (11.3 Kg) per tray, while vacuum pump cycle time decreased. 600 pounds of instruments can be processed in a single cycle of the full-size, 76” Model 833HC-E.

A **screen saver extends the life of the backlit LCD** and saves energy. Touching the panel illuminates and reactivates the display.

The **temperature of the discharge water is controlled** by a temperature device to be less than 140°F (60°C). This switch also conserves cold water by cooling the drain effluent only when it is needed.

Automatic utilities control feature provides a seven-day timer for programmed startup and shut down of the sterilizer. When activated, the Control System automatically shuts OFF water and steam valves to the sterilizer, conserving energy. Cycles running beyond the programmed shutoff time will be completed prior to shut down. Sterilizer utilities can be re-started manually or by programmed time.

ENVIRONMENTAL IMPACT

Getinge steam sterilizers are designed and constructed with our environment in mind. To aid in the conservation of natural resources, and in recognition of prevailing Environmental Policies, particularly ISO 14001, Getinge steam sterilizers are more than 90% (by weight) recyclable. Under normal operation, Getinge steam sterilizers produce no harmful byproducts. The steam sterilization process, in and of itself, produces nothing more than hot drain water.

WARRANTY

Getinge USA, Inc. warrants that each sterilizer is carefully tested and inspected and leaves the factory in proper working condition, free from visible defects. Sterilizers are warranted for one year from the start of the warranty, including parts and labor (excluding expendable parts). The ASME pressure vessel is further warranted to the original owner against structural failure for a period of 15 years from the date of initial operation. See warranty pamphlet for complete details.

MATERIAL HANDLING ACCESSORIES

When the 800 Series sterilizer is installed in a recessed pit, the chamber will be loaded at floor level. Wrapped sets and container sets are arranged on the shelves of the Model 4003 Load / Transfer Cart and loaded directly into the chamber. Each load cart is validated for 12 instrument sets with a weight of 25 Lbs. each. The 42" Model will hold a single cart with 12 sets. The 76" Model will hold two load carts for a total of 24 instrument sets. Order several extra Load Carts to be used for storage prior to sterilization; holding for cool-down following sterilization; and for transportation of sterile goods to surgical suites.

Model 4003 Floor Loading Cart

When the 800 Series sterilizer must be installed directly on the floor, the chamber loading position will be elevated. One solution is to utilize the Model 4004 Transfer Carriage with the Model 4003RC Floor Loading Cart. The 4004 Transfer Carriage is used to support the 4003RC Cart in the proper elevated position while the cart is loaded with instrument sets and wrapped goods. The carriage with load cart is docked with the sterilizer and the load cart is pushed off the carriage into the chamber. This action is reversed to remove the load cart from the chamber. An alternate solution is to order the sterilizer with an integrated SCISSOR LIFT to raise and lower the load cart for loading and unloading operations.

Models 4004 Carriage and 4003RC Load Cart

TECHNICAL DOCUMENTATION

Number	Description
6013078801	800-E Installation Arrangement Drawing Floor Mount, LH Door (CE)
6013095701	800-E Installation Arrangement Drawing Floor Mount, RH Door (CE)
6013095801	800-E Installation Arrangement Drawing Pit Mount, LH Door (CE)
6013095901	800-E Installation Arrangement Drawing Pit Mount, RH Door (CE)
HS04103	800-E Pit Drawing, 42" LH Door (CE)
HS04104	800-E Pit Drawing, 76" LH Door (CE)
HS04105	800-E Pit Drawing, 42" RH Door (CE)
HS04106	800-E Pit Drawing, 76" RH Door (CE)
6013065201	800-E Piping & Instrumentation Diagram
GR101	800 Series Seismic Anchorage, Pit Plan
GR101	800 Series Seismic Anchorage, Floor Plan
HS3472	Water-Saver Arrangement Drawing
HS4134	Electric Water-Chiller Drawing

Getinge Infection Control is the world leading provider of solutions for sterile processing in the healthcare sector. We aim to ensure the highest quality and safety at the lowest total cost. We offer complete solutions for a seamless work-flow, reducing the risk of contamination while helping healthcare to increase efficiency.

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GETINGE
GETINGE GROUP

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